

Claim Listing

Claims 14-16 are pending. Claims 1-13 and 17-33 are canceled. Claims 34-36 are new.

1-13. (Canceled).

14. (Currently amended) A method of performing a clinical trial comprising:
_____ randomizing with a processor study participants into a plurality of treatment

groups;

_____ performing a first phase of testing, said first phase of testing including
administering an active treatment to a first group of said plurality of treatment groups, and
administering a placebo to a remainder of said treatment groups;

_____ determining whether each participant in each of said treatment groups is a
responder or a non-responder;

_____ performing a second phase of testing, said second phase of testing including
administering said placebo to at least one non-responder in at least one group, and administering
said active treatment to at least one non-responder in at least one group; and

_____ analyzing with a processor data from said first phase of testing and from said
second phase of testing

_____ wherein said analyzing comprises determining an effect of active treatment, and
The method of claim 14 wherein said determining an effect of active treatment is
performed in accordance with the formula:

$$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$$

wherein h is the a value representative of
effectiveness of the active treatment, w is a weighting factor, p_1 is the a response rate to the first
administration of active treatment during said first phase, q_1 is the a response rate to the first
administration of placebo during said first phase, p_2 is the a response rate to the second
administration of active treatment during said second phase, and q_2 is the a response rate to the
second administration of placebo during said second phase.

15. (Currently amended) A method of performing a clinical trial comprising:
_____ randomizing with a processor study participants into a plurality of treatment
groups;

_____ performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of said plurality of treatment groups, and administering a placebo to a remainder of said treatment groups;

_____ determining whether each participant in each of said treatment groups is a responder or a non-responder;

_____ performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group; and

_____ analyzing with a processor data from said first phase of testing and from said second phase of testing.

_____ wherein said analyzing comprises determining an effect of active treatment, and ~~The method of claim 11~~ wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w \left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3}+n_{2,3})}{2na} \right) + (1-w) \left(\frac{n_{2,1}}{n_{2,1}+n_{2,2}} - \frac{n_{1,1}}{n_{1,1}+n_{1,2}} \right),$$

wherein h is ~~the~~ a value representative of effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, ~~n is the total number of study participants~~, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $[[n_{3,1}]]$ $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

16. (Original) The method of claim 14 wherein data from said administering placebo to non-responders in said first group is not used in said determining said placebo response rate

17-33. (Canceled).

34. (New) A method of performing a clinical trial comprising:
performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study participants, and administering a placebo to a remainder of said plurality of treatment groups of study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;
determining whether each participant in each of said treatment groups is a responder or a non-responder; and
performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,
wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,
wherein said analyzing comprises determining an effect of active treatment, and
wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w(p_1 - q_1) + (1-w)(p_2 - q_2)$$
, where h is a value representative of effectiveness of the active treatment, w is a weighting factor, p_1 is a response rate to the administration of active treatment during said first phase, q_1 is a response rate to the administration of placebo during said first phase, p_2 is a response rate to the administration of active treatment during said second phase, and q_2 is a response rate to the administration of placebo during said second phase.

35. (New) A method of performing a clinical trial comprising:
performing a first phase of testing, said first phase of testing including administering an active treatment to a first group of a plurality of treatment groups of study

participants, and administering a placebo to a remainder of said plurality of treatment groups of study participants, wherein said study participants have been randomized with a processor into said plurality of treatment groups;

determining whether each participant in each of said treatment groups is a responder or a non-responder; and

performing a second phase of testing, said second phase of testing including administering said placebo to at least one non-responder in at least one group, and administering said active treatment to at least one non-responder in at least one group,

wherein data from said first phase of testing and from said second phase of testing are analyzed with a processor,

wherein said analyzing comprises determining an effect of active treatment, and

wherein said determining an effect of active treatment is performed in accordance with the formula:

$$h = w \left(\frac{n_{3,1}}{n(1-2a)} - \frac{(n_{1,3} + n_{2,3})}{2na} \right) + (1-w) \left(\frac{n_{2,1}}{n_{2,1} + n_{2,2}} - \frac{n_{1,1}}{n_{1,1} + n_{1,2}} \right),$$

where h is a value representative of effectiveness of the treatment, w is a weighting factor, n is the total number of study participants, $n_{1,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to placebo in the second phase, $n_{1,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to placebo in the second phase, $n_{1,3}$ is the number of participants who were responders to placebo in the first phase and were responders to placebo in the second phase, $n_{2,1}$ is the number of participants who were non-responders to placebo in the first phase and were responders to treatment in the second phase, $n_{2,2}$ is the number of participants who were non-responders to placebo in the first phase and were non-responders to treatment in the second phase, $n_{2,3}$ is the number of participants who were responders to placebo in the first phase and were responders to treatment in the second phase, $n_{3,1}$ is the number of participants who were responders to treatment in the first phase, and a is a randomization fraction.

36. (New) The method of claim 34 wherein data from said administering placebo to non-responders in said first group is not used in said determining said placebo response rate.